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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,265	12/09/2003	Stevin H. Zorn	PC10766C	4717

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EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,265	ZORN ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *No IDS filed* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

Priority to US provisional application 60/221,268, filed 27 July 2000, is acknowledged.

Claims 1-9 are currently examined.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,548,502 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a method of treating or preventing novelty seeking disorders by administering a dopamine D4

receptor ligand. In addition, the instant application claims compounds which meet the criteria for the generic compound of U.S. Patent No. 6,548,502 B2 claim 1.

2) Claims 1-9 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-17 of copending Application No. 10/825406 (US Patent Application Publication No. US 2004/0198734 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method of treating substance abuse disorders with the same compounds (compounds of formula 1 in each case).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant needs to file a terminal disclaimer over each of the patents to obviate the rejections. In addition, Applicant is advised to review all pending application for issues of double type patenting. The following is a list of known patents and applications with obviousness type double patenting issues:

US Patent No. 5883094.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3) Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5883094 (Fliri et al).

Fliri et al. teach the instantly claimed compound of claim 1, part (b) for treatment or prevention of CNS disorders (see: abstract). Fliri et al. teaches that the conditions to be treated with the claimed compounds include sexual disorders, impulse disorders, chemical dependencies such as drug and alcohol dependencies (see: col. 3 lines 48-64; claims 10-14). Fliri et al. also teach the compounds listed in instant claims 2-7 for treating or preventing of the conditions (see: col. 1, line 52- col. 4, line 42; col. 12, line 20-end of col. 13, Examples 1-9). Fliri et al. teach that the claimed compounds have dopamine D4 receptor binding activity (see: col. 6, lines 1-5; claims 13 and 14).

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant does not provide enablement for treating or preventing a novelty-seeking disorder in a subject by administering a dopamine D4 receptor ligand.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) Nature of the invention.
2) State of the prior art.
3) Relative skill of those in the art.
4) Level of predictability in the art.
5) Amount of direction or guidance provided by the inventor.
6) Presence or absence of working examples.
7) Breadth of the claims.
8) Quantity of experimentation necessary to make or use the invention based on the content of the disclosure.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1) The nature of the invention.

The claimed invention relates generally to treating as well as *preventing* novelty seeking disorders, such as pathological gambling, attention deficit disorder with hyperactivity disorder, substance addiction, drug addiction, alcohol addiction, and sex addiction.

2) State of the prior art.

While the state of the art is relatively high with regard to the treatment of specific novelty seeking disorders with various, specific multi-modal therapy, for example alcoholism, the state of the art with regard to treating all novelty seeking disorders

broadly with a single agent is underdeveloped. In particular, there is no known agent that is effective for treating all types of novelty seeking disorders. For example, there is no known agent that can treat and cure alcoholism. The Mann reference teaches various pharmacological agents used in treating alcoholism, including dopaminergic agonists as well as antagonists, however the trials have yielded "disappointing results" (see: abstract; p. 494-496, section 4.2). Mann also points out that "the biological basis of alcohol dependence appears to be multifactorial," and " the future of management of alcoholism may be combination therapy" (abstract).

3) Relative skill of those in the art.

The relative skill of those in the art is high, generally that of a PHD/MD.

4) Level of predictability in the art.

The novelty-seeking disorder treatment art involves a very high level of unpredictability as demonstrated by the state-of-the-art with regard to the treatment of novelty seeking disorders, i.e. alcoholism, with specific agents and has long been underdeveloped with regard to the treatment of novelty seeking disorders broadly (see discussion in section *2)* above on the state of the prior art). The lack of significant guidance from the present specification or prior art with regard to the actual treatment of all types of novelty seeking disorders in a mammal, including a human subject, with the claimed active ingredients makes practicing the claimed invention unpredictable.

5) Amount of direction or guidance provided by the inventor & 6) Presence or absence of working examples.

The specification provides no working examples of treatment of any specific

novelty seeking disorder with any specific agent claimed. In addition, regarding claims 8 and 9, applicant does not provide a description all possible agents with dopaminergic activity.

The specification at page 35 states that "utility of the present invention may be determined for the recited dopamine D4 ligands by administering any of the ligands to subjects deemed to be suffering from a novelty seeking disorder as determined from a Temperament and Character Inventory." This statement does not provide guidance as to dosage, administration schedules, or even the particular type of disorder and agent, is to be employed.

7) Breadth of claims.

The claims are very broad and inclusive of any novelty seeking disorder and, claims 8 and 9 in particular are inclusive of any agent with dopamine activity, generally. The breadth of the claims exacerbate the complex nature of the subject matter to which the present claims are directed. The claims are extremely broad due to the vast number of possible disorders represented by the term "novelty seeking disorder" as well as the vast number of agents with dopaminergic activity.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains (i.e. pharmacological treatment and prevention of novelty seeking disorders) to make or use the invention commensurate in scope with the claims. The lack of adequate guidance from the specification or prior art with regard to the actual treatment of all novelty

seeking disorders with dopaminergic agents fails to rebut the presumption of unpredictability existent in this art. Applicants fail to provide the guidance and information required to ascertain which particular type of novelty seeking disorders the claimed agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure with respect to testing an agent against the Temperament and Character Inventory (see specification at page 35) is noted but does not demonstrate treating all cancers.

In addition, regarding the issue of "preventing," the burden of enabling the prevention of a condition such as a novelty seeking disorder, i.e. alcoholism, would be much greater than that of enabling the treatment of the condition. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing novelty seeking disorders or how a patient could be kept from every being susceptible to these conditions. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active agents for preventing novelty seeking disorders.

The term "prevention" is synonymous with the term "curing" and both circumscribe methods of absolute success. Since absolute success is not reasonably possible with most diseases/conditions, especially those having etiologies and pathophysiological manifestations as complex as a novelty seeking disorder such as alcoholism, the specification, which lacks an objective showing that malignant neoplasia can actually be prevented, is viewed as lacking an adequate written description of the same.

Absent a reasonable *a priori* expectation of success for using a specific chemotherapeutic agent/combination to treat any particular type of cancer, one skilled in the art would have to extensively test many various tumor types. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as its is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

Pertinent Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Paterson, AD, et al., "Dopamine D4 Receptor Gene: novelty or nonsense?," July 1999 *Neuropsychopharmacology*, 21: 3-16. This reference discusses the significance and inconclusive results of the role of the Dopamine D4 receptor in novelty seeking disorders, such as alcoholism, drug abuse, and ADHD.

Conclusion

Claims 1-9 are rejected. No claims are allowed.

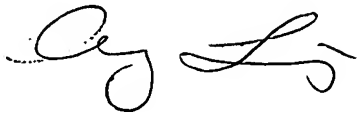
Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614



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